

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
8 April 2004 (08.04.2004)

PCT

(10) International Publication Number
WO 2004/028433 A3

(51) International Patent Classification⁷: **A61N 1/18**
(21) International Application Number:
PCT/US2003/030032

(22) International Filing Date:
26 September 2003 (26.09.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/413,773 27 September 2002 (27.09.2002) US

(71) Applicant (for all designated States except US): **THE GOVERNMENT OF THE UNITED STATES OF AMERICA**, represented by **THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES** [US/US]; National Institute of Health, Office of Technology Transfer, 6011 Executive Blvd., Suite 325, Rockville, MD 20852-3804 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **LUDLOW, Christy, L.** [US/US]; 8801 Garfield Street, Bethesda, MD 20817 (US). **MANN, Eric** [US/US]; 13712 Springdale Drive, Clarksville, MD 21029-1353 (US). **BURNETT, Theresa** [US/US]; 8324 16th Street, #324, Silver Spring, MD 20910 (US). **BIELAMOWICZ, Steven** [US/US]; 1500 Twisting Tree Lane, McLean, VA 22101 (US).

(74) Agent: **GRANADOS, Patricia, D.**; Heller Ehrman White & McCauliffe LLP, 1666 K Street, N.W., Suite 300, Washington, DC 20006-1228 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

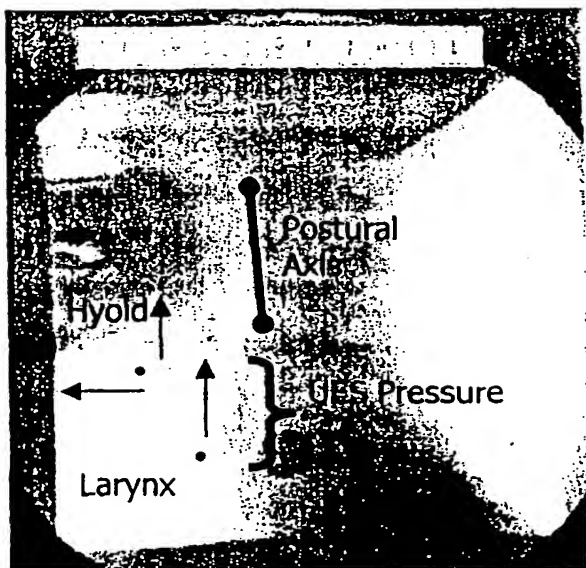
Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) Date of publication of the international search report:
27 May 2004

[Continued on next page]

(54) Title: METHODS AND DEVICES FOR INTRAMUSCULAR STIMULATION OF UPPER AIRWAY AND SWALLOWING MUSCLE GROUPS



(57) Abstract: Devices and methods were discovered that successfully provided patient autonomous control of both hyolaryngeal elevation, anterior hyoid motion and opening of the upper esophageal sphincter for swallowing by intramuscular stimulation of two muscles. The technology allows patient self stimulation of swallowing and can return oral feeding to dysphagia patients. Indwelling electrode stimulation of only two muscles generated as much as 80 % of normal synergistic movement leading to swallowing. The devices and methods also are useful for control of other upper respiratory muscle groups involved in speech and voice. Calibration techniques may be used in combination for greater freedom in setting and using electrodes over extended implantation time periods. These methods and devices can control complex movements of body solids such as bone and cartilage and tissues by electro stimulation of a minimum set of muscles simultaneously.